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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,100	01/03/2002	Michael Edwin Kuehn	N1305-022	5350

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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 04/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8/17 Office Action Summary	Application No. 10/038,100	Applicant(s) KUEHN ET AL.	
	Examiner David T. Fox	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-10 and 33-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 7-10 and 35-48 is/are allowed.
- 6) ☒ Claim(s) 33-34 and 49-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The application should be reviewed for errors. Errors appear, for example, in claim 49, line 3, where "a characteristics" should be replaced with --a characteristic--.

The amendment to claim 8 submitted 12 January 2004 is not in compliance with 37CFR 1.121(c), because newly added material should be underlined when it appears in the reproduced claim. The Examiner apologizes for any confusion caused by his indication on page 2 of the first Office action that claim 8 should be amended to insert --or-- in the last line. The double dashes were intended to indicate the particular word to be inserted. In the interest of compact prosecution, the Examiner will treat claim 8 on the merits. Applicant is requested to submit a correctly amended claim 8 in response to this Office action. The newly amended claim 8 should also contain a period at its end, which period is still missing from claim 8 as amended on 12 January 2004.

The amendments of 12 January 2004 overcome the outstanding rejections under 35 USC 112, second paragraph; the deposit rejection under 35 USC 112, first paragraph; and the art rejections of record.

Claims 33-34 and 49-50 (newly submitted) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Newly submitted claims 33-34 and 49-50 recite a transgenic tomato plant with "improved nutritional quality". However, there is no basis in the specification for this term. Accordingly, the claims are directed to NEW MATTER. Applicant is requested to delete "improved nutritional quality, " from claim 33 in order to obviate this rejection.

Claims 33-34 and 49-52 (newly submitted) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 4-6 of the first Office action for claims 6, 11-13, 15-17 and 19-32.

Claims 33-34 and 49-52 (newly submitted) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated on pages 6-9 of the last Office action for claims 6, 11-13, 15-17 and 19-32.

The claims are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an inbred tomato plant having all of the genetic and morphological characteristics of inbred tomato 294, or transformed or backcross conversion plants thereof, or F1 hybrids produced therewith, as stated in the paragraph bridging pages 13 and 14 of the first Office action.

Claims 1-5, 7-10 and 35-48 are allowed.

Applicant's arguments filed 12 January 2004, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicant urges that the written description and enablement rejections are improper, given the knowledge by those skilled in the art that an F1 hybrid produced by crossing two genetically homogeneous inbreds will be completely defined by its having one-half of the genetic complement of each inbred parent, that backcrossing techniques are well known and predictable means of introducing single gene conversions but otherwise maintaining the morphological fidelity of the original recurrent parent, and the failure of Kraft et al to support the Examiner's position.

The Examiner maintains that claims drawn to F1 hybrids fail to meet the criteria set forth in the Written Description Guidelines, because as much as one-half of their genetic material is from a multitude of non-exemplified, non-characterized parental sources. Furthermore, even the remaining half that is donated by inbred tomato 294 has not been at all characterized. Inbred tomato 294 has only been characterized on the basis of a collection of morphological traits, presumed to be the result of the interaction of multiple genes. However, the genome of inbred tomato 294, comprising tens of thousands of individual genes, has not been sequenced or otherwise characterized. Furthermore, the resultant hybrids have not been morphologically characterized, and could encompass a multitude of traits which differ from those traits present in inbred tomato line 294. Thus, claims drawn to F1 hybrids are inadequately described. Furthermore, as the hybrids are not described, one skilled in the art would not know how to use them, so that they are not enabled.

Regarding backcrossing techniques, the Examiner maintains that the ability of the skilled artisan to obtain a plant which approximates the original recurrent parent does not ensure that the backcross conversion plant is adequately described or enabled within the meaning of 35 USC 112, first paragraph. Since the genome of inbred tomato 294 has not been at all characterized, and since the introgression of another gene will necessarily result in the introduction of uncharacterized genetic material linked to the donor gene of interest, the resultant backcross conversions will be inadequately described in terms of the presence of the linked genetic material, and in terms of any effects the linked genetic material may have on the expression of morphological traits in the resultant tomato plant. Since it is unclear which traits of 294 will be retained and which will be lost in the backcross conversion plant, such a plant is inadequately described. Since it is unknown what traits will be expressed by the backcross conversion plant, one skilled in the art would not know how to use it, so that claims drawn to it are not enabled.

Regarding Kraft et al, the Examiner acknowledges Applicant's characterization, in the paragraph bridging pages 12 and 13 of the response, that the reference teaches that two loci may become fixed for rare alleles. The two loci may be fixed if they are genetically linked, i.e. if the introduction of one of the alleles, conferring a desired trait such as insect resistance, results in the co-introduction of a genetically linked second allele conferring an unknown or undesirable trait, or interfering with the expression of another gene conferring a desirable 294 trait. If one of these rare alleles is not involved in the expression of the desired donor trait, or if one of these rare alleles interferes with

the expression of another desirable trait originally present in inbred tomato line 294, then the resultant conversion plant is inadequately described regarding the presence of uncharacterized genetic material and the effect of that material on trait expression. Such a plant containing genetically linked undesirable loci, conferring unknown or undesirable, non-294 traits, has not been assigned a use by the specification, and so claims directed to such a plant would not be enabled. Thus, the reference indeed supports the Examiner's position.

Furthermore, it is noted that the newly submitted claims 49-50 do not specify the number of generations of backcrossing to the original recurrent parent, wherein fewer than four generations of said backcrossing would result in the retention of significant portions of the genome of the donor parent, which genomic portions are uncharacterized, and which genomic portions would confer a multitude of non-294 traits. Furthermore, it is noted that claims 33-34 and 49-50 are drawn to genes conferring improved nutritional quality in tomato, wherein said genes have not been isolated, identified or described in the instant specification, and wherein the instant specification provides no guidance regarding their introduction into tomato plants or the phenotype of the resultant plants.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1638

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

April 1, 2004

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", with a stylized flourish at the end.